Randomized Controlled Trial of Osteoconductive Fixation Screws for Anterior Cruciate Ligament Reconstruction: A Comparison of the Calaxo and Milagro Screws

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Purpose: To compare the outcome of 2 bioabsorbable screws for tibial interference fixation in anterior cruciate ligament reconstruction with reference to rate of absorption, osteoconductive properties, and clinical outcome. **Methods:** Patients undergoing primary anterior cruciate ligament reconstruction with hamstring autograft in a single unit were invited to participate in this study. Patients were randomized to receive either the Calaxo screw (Smith & Nephew, Andover, MA) or Milagro screw (DePuy Mitek, Raynham, MA) for tibial fixation. Patients were reviewed with subjective and objective evaluation by use of the International Knee Documentation Committee form, Lysholm score, KT-1000 arthrometry (MEDmetric, San Diego, CA), and clinical examination. Magnetic resonance imaging was performed at 1 year and computed tomography scanning at 1 week and at 6, 12, and 24 months. **Results:** Sixty patients agreed to participate in the study, with 32 patients randomized to the Calaxo screw and 28 to the Milagro screw for tibial fixation. There was no significant difference in subjective or objective clinical outcome between the 2 groups. At 24 months, 88% of Calaxo screws showed complete screw resorption compared with 0% of Milagro screws ($P < .001$). Tibial cysts were present in 88% of the Calaxo group and 7% of the Milagro group ($P = .001$). At 24 months, the mean volume of new bone formation for the Calaxo group was 21% of original screw volume. Ossification of the Milagro screw was unable to be accurately assessed as a result of incomplete screw resorption. **Conclusions:** Both screws showed similar favorable objective and subjective outcomes at 2 years. The Calaxo screw resorbed completely over a period of 6 months and was associated with a high incidence of intra-tunnel cyst formation. The Milagro screw increased in volume over a period of 6 months, followed by a gradual resorption, which was still ongoing at 2 years. Both screws were associated with tunnel widening, and neither showed evidence of significant tunnel ossification. We conclude that, despite satisfactory clinical outcomes, the addition of "osteoconductive" materials to bioabsorbable screws is not associated with bone formation at the screw site at 2 years. **Level of Evidence:** Level I, randomized controlled trial.

Interference screw fixation is a popular technique for securing the graft into the bone tunnels during anterior cruciate ligament (ACL) reconstruction. Evolution in the material used to make the tibial screw has occurred because of the potential problems caused by traditional metal screws. The major disadvantages of metal screws are the potential to damage the graft during insertion because of the material's hardness,[1] artifact or "scatter" effects when imaging the knee,[2] and the potential need for removal of the screw in further surgical procedures such as osteotomy. The gold-standard interference screw therefore would be nonmetallic, easy to use, and able to provide strong fixation until the graft incorporates, and then fully undergo bioabsorption to be replaced by bone.

Several types of bioabsorbable screws have been developed. Poly-L-lactide (PLLA) screws have been

Table 1. Summary of Inclusion and Exclusion Criteria for Patients Recruited to Trial

Inclusion Criteria	Exclusion Criteria
1. Undergo primary ACL reconstruction under the care of the senior authors 2. Be aged between 18 and 60 years 3. Be willing to participate in a randomized controlled trial and provide written informed consent 4. Be willing and able to attend clinic for all postoperative assessments 5. Be willing and able to undergo CT scans at all postoperative assessments 6. Live in Sydney metropolitan area	1. Previous ACL reconstruction to either knee 2. Contralateral ACL deficiency 3. Any concurrent ligamentous injury or significant pathology to index knee, ligamentous laxity >5 mm in same knee 4. Anyone seeking compensation for their injury 5. Evidence of full-thickness chondral damage or degeneration 6. Presence of any other medical condition that may adversely influence patient's healing postoperatively 7. Pregnancy before surgery or during follow-up period

used in ACL surgery for about 10 years with good clinical results, but there is evidence of tunnel widening and a lack of bony ingrowth.[3-6] In addition, there have been concerns about late inflammatory reactions to the PLLA screw, which may be related to the inherent crystallinity of the material.[7] These potential problems have led manufacturers to provide materials that are more osteoconductive. Two of these newer products are the Calaxo screw (Smith & Nephew, Andover, MA) and the Milagro screw (DePuy Mitek, Raynham, MA).

The Calaxo screw is a blend of poly(D,L-lactide—co-glycolide) (PDLG) and calcium carbonate in a ratio of 65%:35%. PDLG is a bioabsorbable polymer that has been used as a material to make interference screws for many years. Lajtai et al.[8] have shown safe and effective outcomes at a minimum of 2.5 years after surgery with PDLG screws. The addition of calcium carbonate to the screw has the purpose of neutralizing the acidity of the degradation products of PDLG while encouraging osteoconduction. Calcium carbonate is a normal component of bone and is effective as a bone graft substitute in large animal models and humans.[9] Smith & Nephew has termed this material poly-lactide carbonate, and the preliminary studies in sheep have been promising, showing adequate mechanical strength at 12 weeks and successful bony ingrowth by 52 weeks.[10]

The Milagro screw is a blend of poly(lactide—co-glycolide) and tricalcium phosphate in a ratio of 70%:30%. TCP has also been used successfully as a bone graft substitute in humans. Animal studies have shown that this combination of materials has resorption and bone replacement properties superior to PLLA. In a dog model, the Milagro screw showed evidence of early resorption at 3 months, progressing to marked resorption at 18 months. Newly formed bone in the drilled tunnels was evident at 24 and 36 months postoperatively.[11]

The aim of this study was to compare the use of 2 bioabsorbable screws designed for interference fixation in humans undergoing primary arthroscopic ACL reconstruction with hamstring tendon autograft, with particular interest in clinical outcome, screw resorption, and ossification within the tibial tunnel. We hypothesized that the Calaxo screw would be resorbed more quickly than the Milagro screw but clinical outcome would be comparable and that both screws would be resorbed by the body after 12 months.

Methods

Patient recruitment was from all patients undergoing primary ACL reconstruction in our unit. Inclusion and exclusion criteria for the study are listed in Table 1. Ethical approval was sought and granted by a local ethics committee (St. Vincent's Hospital, Sydney, Australia).

Two surgeons, using the same operative technique, performed the surgery. This was a single-incision, arthroscopic technique using 4-strand hamstring tendon autograft and anteromedial-portal femoral tunnel drilling. Femoral graft fixation was performed with a titanium interference screw, which has been shown to produce excellent long-term results.[12] The tibial tunnel fixation was the only variable, using either the Calaxo screw or the Milagro screw. A computerized random-number generator was used to create randomization into 1 of 2 groups, and cards in sealed envelopes were prepared, attached to the patient notes, and opened immediately before the procedure once the patient had entered the theater. Once the patient had been assigned to 1 of the 2 groups, the card was returned to the patient notes in another sealed envelope and not opened again until the trial was concluded. This way, neither the patient nor the clinical assessors knew which screw had been implanted into which patient. Patients receiving the Calaxo screw formed group 1 of the trial, and patients receiving the Milagro screw formed group 2.

Patients were permitted to bear weight as tolerated on crutches immediately after surgery, and no brace was used. An accelerated rehabilitation program was instituted. Return to competitive sports involving jumping, pivoting, or sidestepping was prohibited until 6 months after the reconstruction and then was allowed only after rehabilitation goals had been met. Patients were reviewed in the clinic at 1 and 6 weeks and at 6, 12, and

24 months. Computed tomography (CT) scans were performed at 1 week and at 6, 12, and 24 months. Magnetic resonance imaging (MRI) scans were performed at 1 year. Assessments using objective and subjective scoring systems were carried out at 6 weeks and at 3, 12, and 24 months. These examinations and investigations are summarized in Table 2.

Subjective evaluation was performed with the Lysholm questionnaire and International Knee Documentation Committee (IKDC) forms completed by the patients at 12 and 24 months. Ligament stability was assessed with instrumented laxity testing by use of the KT-1000 arthrometer (MEDmetric, San Diego, CA) manual-maximum test at 30° of flexion. The Lachman and pivot-shift tests were used, and all assessments were graded as the difference from the normal contralateral side. The Lachman test was graded as 0 (<3 mm), 1 (3 to 5 mm), or 2 (>5 mm); the pivot-shift test was graded as 0 (negative), 1 (glide), 2 (clunk), or 3 (gross).

An independent musculoskeletal radiologist evaluated MRI scans at 1 year. Screw resorption, bone marrow edema, and the presence or absence of a ganglion were evaluated. The CT scans were evaluated at a separate radiologic center (Cleveland Clinic, Cleveland, Ohio). From each patient time point, the DICOM (Digital Imaging and Communications in Medicine) series with the highest spatial resolution was converted to a single volume (VFF file format) by use of DICOM conversion software developed in house. Subsequently, for each patient, the time point with the smallest voxel volume was identified (time point A), cropped to include the proximal tibia (encompassing the entire tunnel), and realigned such that the tunnel was oriented parallel to the volume's z-axis (MicroView [GE Healthcare, Buckinghamshire, England] and Vol-Suite [Ohio Supecomputer Center, Columbus, OH]). All other time points for this particular patient were then volumetrically registered to this realigned time point A using a mutual information algorithm (simplex optimization) with software developed in house. The resulting registered volumes were resampled to conform with the voxel resolution of the realigned time point A by use of trilinear interpolation. In this manner, all of the patient images were aligned to a standard orientation, and within each patient dataset, all of the

time points have the same spatial resolution. This enables direct comparison of all imaging time points for all patients.

Measurements of the tibial tunnels on CT images included tunnel length, tunnel volume, and tunnel diameter. Image segmentation was accomplished by fitting a spline just inside the cortical edge of the tunnel at 10-slice intervals and then interpolated for non-splined slices (MicroView). Splines were traced to include the complete tunnel and screw. The starting point was selected as the slice that contained the first fully formed tunnel (complete circle/oval). The tunnel length was held constant over all time points.

For analysis of tunnel diameter, a Euclidean distance map was generated for each tunnel slice in which each tunnel pixel value was converted to that pixel's distance to the nearest tunnel boundary pixel.[13] Thus the value of the pixel at the tunnel's center of mass represents the average diameter for a given tunnel slice. Calculating this number for every slice along the z-axis of the tunnel (the tunnel is oriented parallel to the z-axis for each patient scan) allows the mean tunnel diameter to be determined. The maximum and minimum diameters for each time point are then recorded. The proximal, midtunnel, and distal tunnel measurements are also given. We calculated change from baseline in cubic millimeters or millimeters and percentage of baseline value for each metric. Change from baseline could not be calculated for those patients without early postoperative scans. The calculations of "change from previous" were performed by comparing each time point with the most recently available time point. For patients with missing time points, the comparison may be to 2 "visits" earlier. The mean tunnel attenuation in Hounsfield units was also calculated as a measure of dissolution of the screw.

The primary endpoint was measurement of bony ingrowth into the tibial tunnel and area of the screw postoperatively by use of radiologic software. Secondary endpoints were clinical and subjective outcome as assessed by the IKDC evaluation, KT-1000 arthrometer measurement, Lysholm knee scoring, presence or absence of effusion, and kneeling pain.

Statistical Analysis

We initially planned to recruit 50 patients into each group for the study. Power calculations determined that, to detect a 20% variation in new bone formation with a power of 0.8 and a significance level of $P = .05$, 42 patients were required for each group. By oversampling by an additional 8 patients in each group, we were accounting for the potential for withdrawals and loss to follow-up. Statistical analysis was performed with SPSS software for Windows (IBM, Armonk, NY). All data were assumed to be nonparametric. Statistical significance was set at $P = .05$. Comparison of variables between

Table 2. Summary of Investigations Performed and Their Time Points

Investigation	1 wk (±4 d)	6 mo (±28 d)	12 mo (±28 d)	24 mo (±28 d)
Clinical examination	Yes	Yes	Yes	Yes
IKDC evaluation	No	Yes	Yes	Yes
Lysholm knee scoring	No	Yes	Yes	Yes
KT-1000 arthrometer testing	No	Yes	Yes	Yes
MRI scanning	No	No	Yes	No
CT scanning	Yes	Yes	Yes	Yes

groups was analyzed with χ^2 tests for categorical data and independent-samples t test data. Linear variables were summarized by the mean, and categorical variables were summarized by the frequency.

Results

Patients Demographics

Patient recruitment into the trial began in 2006. In August 2007, midway through the trial, the Calaxo screw was withdrawn by the manufacturer because of a 0.3% incidence of pretibial soft-tissue swelling. As a result, the recruitment for the trial ceased. All remaining patients in the trial after this time point were followed up for 2 years postoperatively. There were a total of 60 patients.

In group 1 (Calaxo) there were 28 patients (19 men and 9 women) with a mean age of 34 years (range, 20 to 52 years). In group 2 (Milagro) there were 32 patients (23 men and 9 women) with a mean age of 33 years (range, 19 to 49 years). There was no statistical difference between groups for any of the patient demographics (sex, age, left v right knee). Fig 1 summarizes recruitment through to follow-up of patients.

MRI Evaluation at 1 Year (n = 53)

Of the 60 patients, 53 (88%) had an MRI scan performed at 1 year. There was complete screw resorption

seen on MRI in 88% of group 1 patients and 0% of group 2 patients ($P < .001$) (Fig 2).

Tibial ganglia of varying sizes were seen in 88% of cases in group 1 compared with 7% of cases in group 2 ($P = .001$). Tibial peritunnel bone marrow edema was seen in 33.3% of cases at 1 year in group 1 and 31% of cases in group 2 ($P = .771$). New bone formation was virtually undetectable in both groups and thus unquantifiable on the MRI scan evaluation.

CT Evaluation (n = 50)

Of the 60 patients, 50 (83%) had a CT scan performed at 1 week and at 6, 12, and 24 months.

Screw Dissolution

There was evidence of dissolution of both types of interference screws with different rates. After 6 months, none of the Calaxo screws could be identified as discrete structures (Fig 3); only a poorly defined, amorphous structure, slightly higher in attenuation than surrounding soft tissue, could be seen. At 24 months, a slight increase in mean attenuation was noted, perhaps related to the new bone formation that occurred in some patients (Fig 4).

The Milagro screws persisted as well-defined structures on CT images at 6 months and had, on average, increased in size (Fig 3). At 12 months, the edges of the screws appeared less well defined, and there was
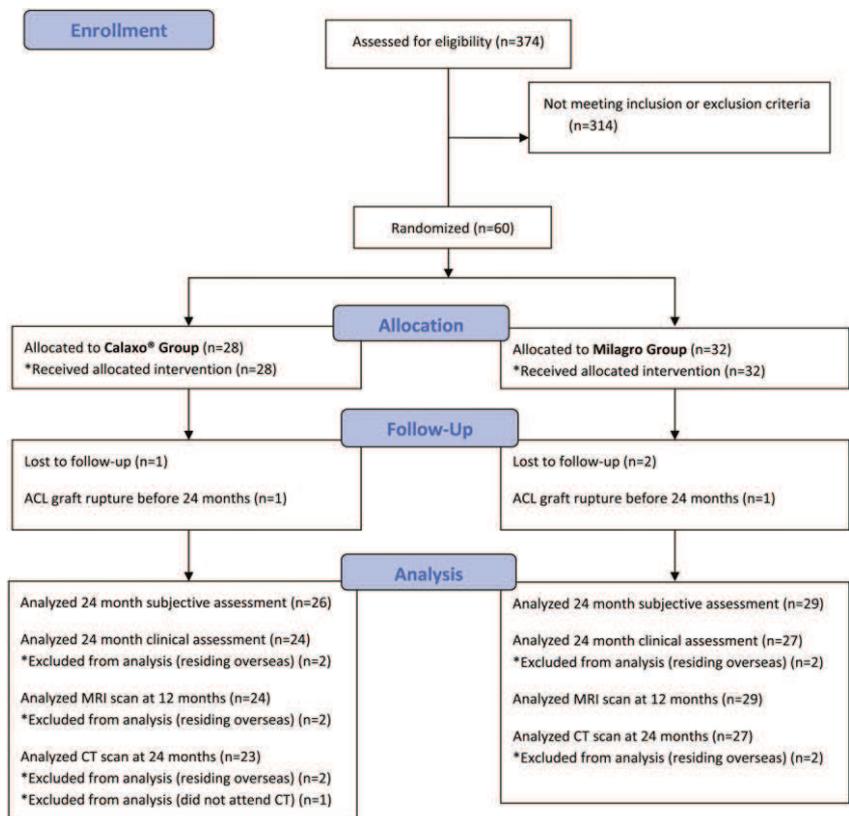

Fig 1. Patient flowchart showing recruitment, exclusion, randomization, and follow-up.
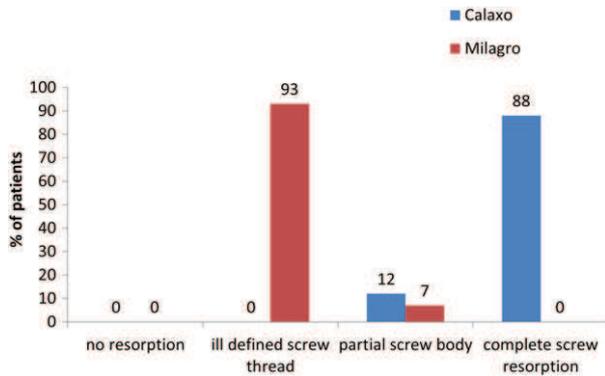
Fig 2. MRI evaluation of screw resorption at 1 year.

Fig 4. Different rates of resorption of screws as measured by changing attenuation on CT scan. The Calaxo screw resorbed more quickly than the Milagro screw.

a variable decrease in size along with diminished CT attenuation (Fig 4). At 24 months, there was a marked decrease in screw volume with a variable amount of fragmented screw material remaining visible.

Tunnel Expansion

Total tunnel volume increased in both groups at 6, 12, and 24 months when compared with the volume at week 1. This was significantly higher in group 1 than in group 2 at 6 months ($P = .005$) and at 24 months ($P < .001$). The results are summarized in Fig 5, and an example of the screw dissolution/tunnel expansion from group 1 (Calaxo) is shown in Fig 6 and an example from group 2 (Milagro) is shown in Fig 7.

New Bone Formation

New bone formation within the original site of the screw could not be accurately quantified for the Calaxo group at 6 months or for the Milagro group at any time point. At 12 months, in the Calaxo group, new bone formation measured an average of 54 mm³, or 6%

(median, 1%) of the original screw volume. This increased to 155 mm³, or 21% (range, 3% to 65%; median, 17%), at 24 months. Of the 24 patients with CT examinations at 24 months, 19 had greater than 10% and 5 had greater than 30% of the original screw site replaced with new bone. Visual inspection of the tunnels containing Milagro screws on CT showed evidence of bone formation within the screw site for some of the patients. There was only minimal new bone formation (<5% of total tunnel volume) within the tunnel outside of the site of the screw for either type of screw.

The margins of the tibial tunnels showed progressive cortication that was similar in both groups (Fig 8). One week postoperatively, approximately 9% of the surface area of the tunnels had CT attenuation similar to cortical bone, which may have been from compaction of trabecular bone during screw placement. The degree of cortication increased with time to a mean of 51%
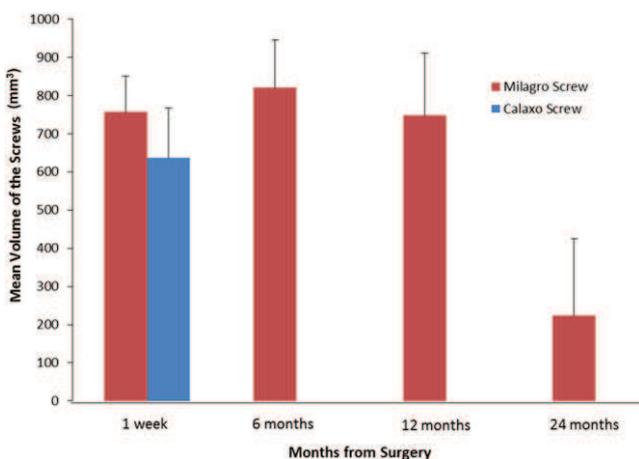

Fig 3. Mean volumes of screws. At 6 months and beyond, the Calaxo screw volumes could not be measured because the screws had undergone significant dissolution. The Milagro screws showed expansion at 6 months before dissolution began.
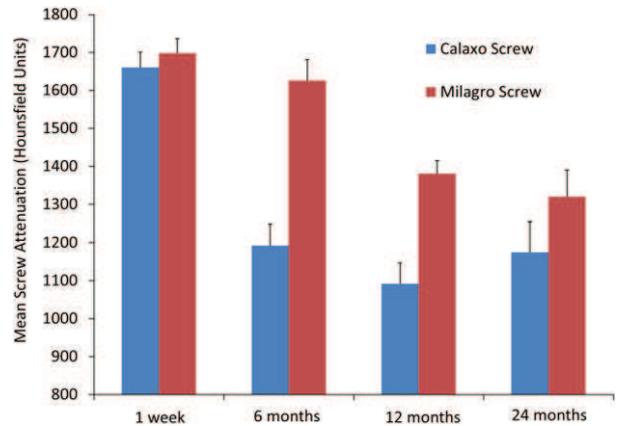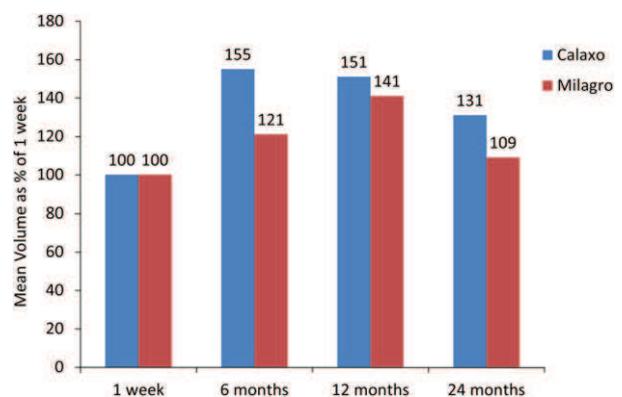

Fig 5. CT scan evaluation of tibial tunnel volume as a percentage at 1 week (postoperatively) and at 6, 12, and 24 months. There was a significant difference between the groups at 6 months ($P = .001$) and 24 months ($P = .02$) but not at 12 months ($P = .350$).
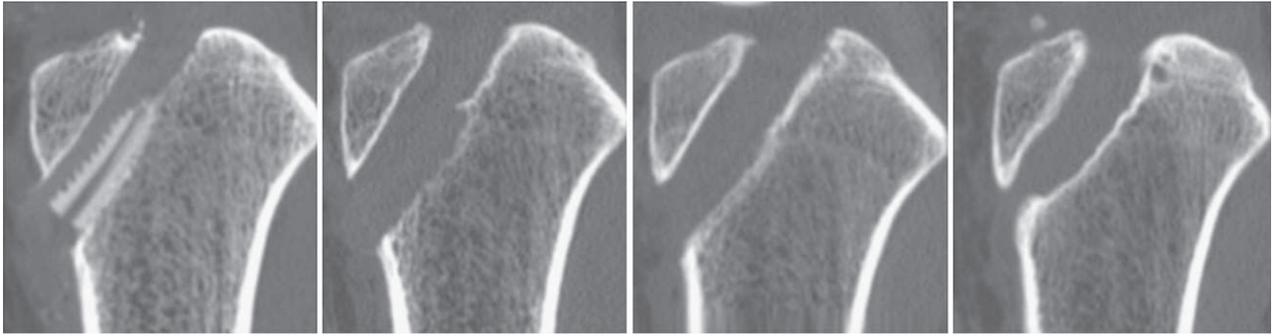
Fig 6. Sagittal CT scans from same patient with Calaxo screw at 1 week and at 6, 12, and 24 months (from left to right), showing rapid dissolution but subsequent tunnel volume expansion.

(median, 51%; range, 19% to 99%) at 24 months with no statistical significance between the 2 groups.

Subjective Outcome (n = 55)

Of the patients, 55 (95%) completed the Lysholm and IKDC scoring evaluation at 24 months. The mean Lysholm score in the Calaxo group was 95 (SD, 5) compared with 96 (SD, 7) in the Milagro group ($P = .602$). IKDC scores were also not significantly different: 92 (SD, 10) in the Calaxo group compared with 94 (SD, 6) in the Milagro group ($P = .291$).

IKDC Clinical Assessment (n = 51)

The IKDC clinical assessment consists of 3 groups of grades: effusion, range of motion, and ligament evaluation.

Effusion. At 24 months from surgery, no knee effusion was present in 22 of 24 patients (92%) in the Calaxo group and 24 of 27 patients (89%) in the Milagro group ($P = .895$). The remaining patients in each group had a mild effusion evident on examination.

Range of Motion. A passive-motion extension deficit of 3° to 5° was recorded in 1 patient in the Calaxo group and 1 patient in the Milagro group. All other patients in both groups had full passive-extension range of motion ($P = .37$). One patient in the Milagro group had

a flexion deficit of 10°, whereas all other patients had normal passive-flexion range of motion.

Ligament Testing. Pivot-shift testing was recorded as grade 0 in 23 of 24 patients in the Calaxo group and 25 of 27 patients in the Milagro group ($P = .62$). In the remaining patients, a grade 1 pivot-shift test was recorded. At 24 months from surgery, the mean side-to-side difference on manual-maximal testing with the KT-1000 arthrometer was 1.8 mm (SD, 2) in the Calaxo group and 2.5 mm (SD, 1.4) in the Milagro group ($P = .16$).

Overall IKDC Grade. The worst grade from each of the group IKDC grades determines the overall IKDC grade. This was classified as normal in 12 of 24 patients in the Calaxo group and 14 of 24 patients in the Milagro group ($P = .90$). A nearly normal examination was recorded in 12 patients in the Calaxo group and 13 patients in the Milagro group ($P = .90$).

Complications

Two patients, one from each group, sustained a graft rupture before 2 years. In group 1 the graft rupture occurred at 4 months in a male patient while playing soccer, and in group 2 rerupture occurred in a male patient while performing martial arts at 2 months (both outside our normal rehabilitation regimen). There was 1 contralateral ACL rupture at 15 months (group 1) and
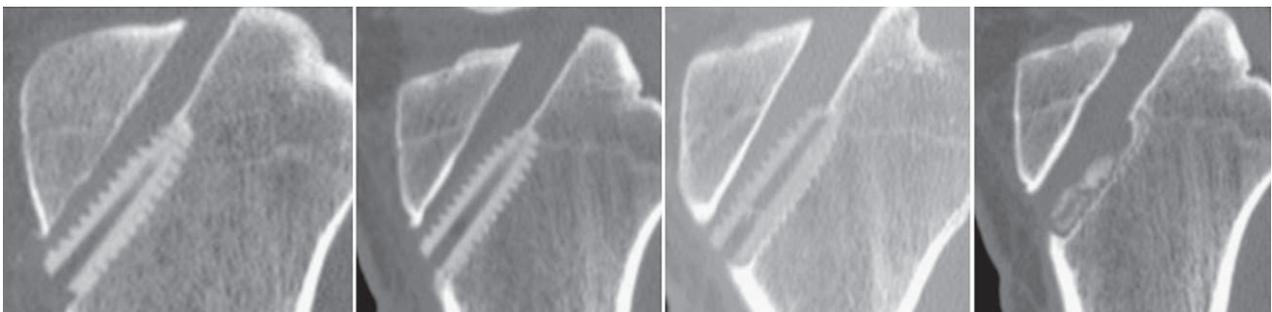

Fig 7. Sagittal CT scans from same patient with Milagro screw at 1 week and at 6, 12, and 24 months (from left to right), showing slow dissolution and tunnel volume expansion.
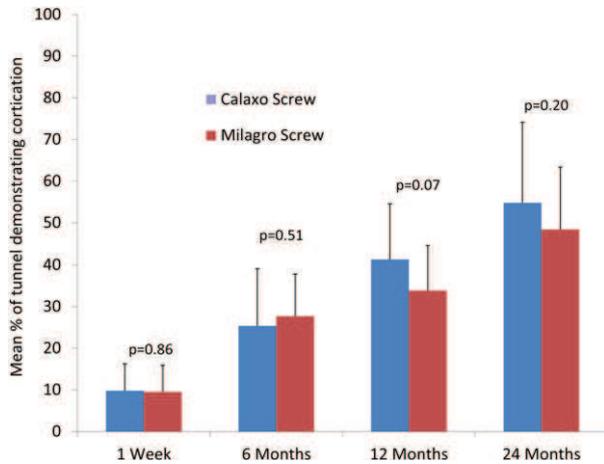
Fig 8. Percentage of tunnel surface with CT attenuation of cortical bone, showing a similar increase for both groups (no statistical significance).

1 excision of a ganglion cyst at 9 months (group 1). The ganglion presented as a hard, subcutaneous cystic swelling overlying the distal tibial tunnel that was clearly visible also on MRI (Fig 9). Excision was straightforward, but the ganglion did recur within 6 months; however, it was not symptomatic, and the patient chose to have it treated nonoperatively.

Discussion

As hypothesized, both the Calaxo and Milagro screws showed good objective and subjective outcomes at 2 years. The Calaxo screw did absorb more quickly than the Milagro screw but of concern was the tunnel widening observed with both screws, and only minimal new bone formation was recorded.

The manufacturer of the Calaxo screw advertises rapid dissolution of the screw, and our study confirmed this with 88% of the screw completely dissolving by 1 year. However, this dissolution was not replaced by bone as in the ovine model.[10] Instead, it caused osteolysis, leading to tunnel expansion, with a mean of 131% of the original tunnel volume at 2 years. We also observed cystic formation in 88% of cases on MRI at 1 year. Although there was only a single case that required further surgery to remove the ganglion, this did represent 1 of 26 total cases (3.8%) presenting for follow-up at 2 years. Other authors have found similar problems with cystic formation in the tibia with the Calaxo screw[14-16] and tunnel widening,[17] although none of these studies reported any significant adverse clinical outcomes. An in vitro study of poly-lactide carbonate has suggested that the rapid dissolution of the polymer is too fast to be buffered by the calcium carbonate and there is a significant pH drop.[18] This may be more pronounced in humans than in the ovine model, and thus these in vivo conditions in humans are more conducive to promoting osteolysis than ossification in the initial period.

The Milagro screw has also been reported as having fast resorption and bony ingrowth to replace the volume loss by 12 months.[19] Another study has reported similar findings with regard to resorption but a slower ossification rate, showing that 81% of patients had evidence of ossification but only 19% had complete ossification at 3 years.[20] These findings are in sharp contrast to our study, which showed that 93% of

Fig 9. Tibial ganglion seen at 9 months after surgery, arising from tibial tunnel on MRI (left), lying subcutaneously (top right), and fully excised with its pedicle (bottom right).

cases had only slight evidence of resorption at 1 year and none of the screws had completely resorbed. Measuring new bone formation accurately was thus difficult because on the CT scans, the attenuation of bone and the attenuation of the unresorbed screw are similar. However, on both MRI and CT, there was very little or no evidence of ossification at 1 year in 93% of cases, and the remaining 7% had some ossification present but it was discontinuous. This group also showed tunnel widening at 6, 12, and 24 months.

When we compared the 2 screws, the Milagro screw did dissolve more slowly than the Calaxo screw ($P = .001$) and was associated with less tunnel widening at 6 and 24 months. There were cystic swellings observed in both groups, but the incidence was much higher in the Calaxo group than in the Milagro group ($P < .001$). Despite these observations, the clinical evaluation showed no significant difference, with good outcomes in both groups. This was the most interesting finding in some respects because, with tunnel expansion and cystic formation, one might expect graft loosening or failure, but this was not observed. Explaining this without histologic analysis is difficult, but it seems that the graft is able to incorporate and retain strength despite a biochemical environment that does not favor bone.

Ossification and cortication of the tunnel appear to be ongoing in both groups. With the Calaxo screw, ossification increased from 6% at 12 months to 22% at 24 months. Similar measurements could not be made with the Milagro screw because of the ongoing presence of the screw, which has a similar attenuation value to bone, making accurate assessment of bone volume impossible. Only once the screw has fully resorbed can accurate inferences regarding bone formation be made. With the Milagro screw, this process is still continuing at 2 years. Tunnel cortication is also ongoing, with 51% of the tunnels showing cortication at 2 years. Once full cortication of the tunnel is complete, new bone formation is unlikely to progress. Therefore longer follow-up of these screws is important, and the extent of final ossification is as yet undetermined.

The major limitation to acknowledge for this study is in the statistical analysis used to compare the 2 screws. Because of the withdrawal by the manufacturer of the Calaxo screw in 2007, we were unable to recruit the necessary study sample to achieve the necessary power for accurate statistical analysis. Despite this, we have found statistically significant differences between the groups.

Conclusions

Both screws showed similar favorable objective and subjective outcomes at 2 years. The Calaxo screw resorbed completely over a period of 6 months and was associated with a high incidence of intra-tunnel cyst

formation. The Milagro screw increased in volume over a period of 6 months, followed by a gradual resorption, which was still ongoing at 2 years. Both screws were associated with tunnel widening, and neither showed evidence of significant tunnel ossification. We conclude that, despite satisfactory clinical outcomes, the addition of "osteoconductive" materials to bioabsorbable screws is not associated with bone formation at the screw site at 2 years.

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